510(K) SUMMARY

OCT 1 6 2009

510(K) Number K091780

5.1 Applicant's Name:

MediGuide Ltd.
Advanced Technology Center, POB 15003, Haifa, Israel
Tel: +972-4-8137000
Fax: +972-4-8550412

5.2 Contact Person:

Jonathan S. Kahan, Esq.
Hogan & Hartson, L.L.P.
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004-1109
Tel: (202) 637-5794
Fax: (202) 637-5910
Mail: JSKahan@hhlaw.com

And/Or

Merav Yarmus, Ph.D.
BioMedical Strategy (2004) Ltd.
7 Jabotinsky Street.
Ramat Gan 52520, Israel
Tel: +972-3- 6123281
Fax: +972-3-6123282
Mail: merav@ebms.co.il

5.3 Date Prepared:

June, 2009

5.4 Trade Name:

Guided Measurement Catheter (GMC™)

5.5 Classification Name:

Diagnostic intravascular catheter

5.6 Product Code:

DQO

5.7 Device Class:

II

5.8 Regulation Number:

870.1200

5.9 Panel:

Cardiovascular

5.10 Predicate Devices:

- Eagle Eye™ Gold IVUS Catheter and Volcano VH IVUS System [Volcano Corp.] cleared under K051337; hereinafter: Eagle Eye Catheter.
- Metricath System [Angiometrx Inc.] cleared under K042685.
- CS RefStar Catheter [Biosense Webster Inc.] cleared under K080425; hereinafter: RefStar Catheter.

5.11 Intended Use / Indication for Use:

The Guided Measurement Catheter GMC™ device is a gMPS™ enabled intravascular catheter intended for the diagnostic evaluation of the coronary vasculature in patients who are candidates for coronary angiography and/or Percutaneous Coronary Intervention (PCI).
The GMC™ is used with compatible gMPS™ system to enable real-time tip positioning and navigation, quantitative length measurement, 3D lumen reconstruction, qualitative 3D foreshortening indication, and landmarking.
The System is indicated for use as an adjunct to fluoroscopy.

5.12 Device Description:

The Guided Measurement Catheter (GMC™) is a Medical Positioning System (gMPS™) enabled coronary diagnostic catheter designed to allow catheter tracking during a routine diagnostic catheterization of the coronary arteries using the MediGuide's gMPS™ system. The catheter includes an embedded gMPS™ sensor in order to allow its tracking by the gMPS™ system.
The GMC™ gMPS™ enabled catheter is intended to be used during a percutaneous coronary procedure, and similarly to an IVUS assessment, inserted to a target coronary artery, usually past a stenotic region, and then pulled back manually, to screen the

selected arterial segment. As the pullback is completed, the 3D trace of the catheter's trajectory is reconstructed and displayed separately in a 3D display, and also superimposed on the 2D X-ray image by the gMPS™ system. The superimposed trace, the Smart Trace, is color coded to show an indication of the angular percent of foreshortening of the artery as it exists in the respective X-ray image. A model of the artery's lumen is automatically generated by the gMPS™ system from only one X-ray image, taken from a single angle (projection).

5.13 Substantial Equivalence:

The intended use and indications for use of the GMC™ catheter are similar to predicate devices. In addition, the GMC™ catheter has substantially similar technological characteristics as well as principles of operation to the predicate devices. Specifically, the GMC™ and its predicates working in conjunction with a computerized system, such as a tracking system, thus providing the user with diagnostic information, including information on its position, enabled by the computerized system.

A set of bench, animal and clinical testing was performed in order to demonstrate the safety and performance of the GMC™ and to verify that it does not raise any new safety and effectiveness issues in comparison to its predicate devices.

Tests results indicated that the GMC™ is as safe and effective as its predicate devices for its intended use and is substantially equivalent to its predicate devices without raising any new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

OCT 16 2009

MediGuide, Ltd.
c/o Mr. Jonathan S. Kahan
Partner
Hogan & Hartson LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004

Re: K091780
Trade/Device Name: GMC™ Guided Measurement Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II (two)
Product Code: DQO
Dated: October 8, 2009
Received: October 8, 2009

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K091780

Device Name: Guided Measurement Catheter (GMC™)

Indications for Use:

The GMC™ device is a gMPS™ enabled intravascular catheter intended for the diagnostic evaluation of the coronary vasculature in patients who are candidates for coronary angiography and/or Percutaneous Coronary Intervention (PCI).

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The System is indicated for use as an adjunct to fluoroscopy.

Prescription Use __√_____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) 10/16/09

Division of Cardiovascular Devices

510(k) Number K091780